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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,495	12/30/2003	Charles R. Roe	BHCS:1007RCE	8734

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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,495	ROE, CHARLES R.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19-47 and 49-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,19-47 and 49-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/9/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/18/08 has been entered.

The response filed on **8/18/08** presents remarks and arguments to the office action mailed on **4/17/08**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 9/9/08 is acknowledged and has been reviewed.

Claim Status

Claims 17, 19-47 and 49-57 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 23-25, 34-44 and 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Garzia US 3,697,563.

Garzia teaches that ξ(3,4,5- trimethoxybenamido)-heptanoic acid in the treatment of cardiac disorders such as cardiac ischemic or cardiac infarction, see col. 2, lines 12 and lines 49-59. It is anticipated that with these disorders result in cardiac muscle weakness because a heart attack occurs when the supply of blood and oxygen to an area of heart muscle is blocked, thus creating weakness to the heart muscle (claims 23-24). Claim 25 is anticipated as a reduced efficiency of a metabolic pathway will be detected once there is a cardiac disorder as required by instant claim 25. The reference also discloses the administration via enterally. Enteral is any form of administration that involves any part of the gastrointestinal such as orally, see col. 3, lines 29-30, therefore the limitations in claims 34-37and 43-44 are disclosed therein. With regard to instant claims 38-41 and 46 the reference teaches the administration parenterally via intravenous administration, see col. 3, lines 29-31. Claim 47 is anticipated with regards

to providing fuel to the heart. Fuel to the heart would be provided an inherent mechanism that would occur by administering the same composition).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 17, 19-47, 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garzia US 3,697,563 in view of Jandacek et al., US 4,753,963 and Jones et al. British Med. J. 1961, 1276-1278.

Garzia is applied here as above. The reference fails to teach the n-heptanoic acid is a triglyceride comprising triheptanoin, the limitations set forth in claims 19-20, 22, 50, 52 and the varying doses as set forth in instant claims 26-33 and 42.

Jandacek et al. teach a triglyceride formulation wherein the amount of the triglyceride utilized in the composition is a nutritionally effective amount, based upon the subject and the nutritional benefits required. The composition typically comprises the

nutritional fat (triglyceride) in an amount of about 2% to about 20% by weight of the composition (about 18 to about 180 calories per 100 grams of composition or about 4% to about 36% of the total caloric value of the composition). See column 5, lines 18-20 and column 7, lines 5-8. It is assumed that the dosages are per day (24 hours).The reference discloses oral and feeding tube administration of the composition. See column 4, line 65-66 as in claim 46. With regard to instant claim 22 and 50 one can infer from the teaching that the methyl esters are easily formed and a chemist would be able to make the ester easily, see col. 3, lines 61-68. Jandacek also discloses parenterally administrable compositions. See column 6, lines 56-60. The reference also discloses the triglyceride may be triheptanoin as R1 and R2 may be n-heptanoyl., see abstract. Triheptanoin is metabolized by the body to three molecules of heptanoic acid and glycerol. Therefore, administration of a composition comprising triheptanoin is equivalent to administration of a composition comprising heptanoic acid. As to instant claim 47, with regards to providing fuel to the heart (it is assumed that providing fuel to the heart would be obvious because anytime that the claimed composition is administered, fuel would be provided an inherent mechanism that would occur by administering the same composition), it is assumed that theses agents will function the same since they are employed for the same treatment condition.

Jones et al. is added to show fat mal-absorption in congestive heart failure, thus, motivating one of ordinary skill in the art to administer the formulation of Jandacek et al to patients with fat malabsorption because Jones et al. teach that fat malabsorption are found in patients with congestive heart failures. See entire doc. of Jones et al.

One of ordinary skill in the art would have been motivated to substitute the compound formulation with ξ(3,4,5- trimethoxybenamido)-heptanoic acid in Garzia to the formulation of Jandacek (see supra) and employ in the treatment of cardiac disorders because the Jones reference teaches that fat malabsorption is found in patients with cardiac disorders and thus any cardiac disorder results in cardiac muscle weakness. One of ordinary skill in the art would have expected success ion employing the formulation of Jandacek to treat cardiac disorders. With regards to the doses as required and addressed in Jandacek above, the determination of a dosage having the optimum therapeutic index is well within the level of the ordinary skill in the art, and the artisan would be motivated to determine the optimum amounts to get the maximum effect of the drug, hence the reference makes obvious the instant invention.

Claims 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garzia US 3,697,563 in view of Jandacek et al., US 4,753,963 and Jones et al. British Med. J. 1961, 1276-1278 as applied to claims 17, 19-41 and further in view of Niezen-Koning J. Inher. Metab. Dis 18, 1995, 230-232 and Bach et al. (Am. J. Clin. Nutri. 1982; 950-962).

The above references and rejection is applied here below. However the references do not explicitly teach the limitation "severe translocase deficiency" in claim 53. It is the understanding that translocase deficiency is the inability to transport lipid to the mitochondria.

The Niezen-Koning reference teaches that a total of 13 inherited/3-oxidation defects have been described and among those 13 disorders there are four that affect the transport into mitochondria of long-chain fatty acids that are activated to their CoA esters. Defects have been described for the plasma-membrane carnitine transporter and carnitine palmitoyltransferase types 1 and 2 (CPT I and II). Three patients have been described with a carnitine-acylcarnitine translocase deficiency, a defect in the transfer of fatty acylcarnitines across the inner mitochondrial membrane in exchange for free carnitine. Along with supportive treatment, treatment was started with carnitine. Dietary treatment consisted of a low-fat diet supplemented with MCT (medium-chain triglycerides).

The Jandacek reference teaches long chain fatty triglycerides do not typically provide well absorbed forms of essential fatty acids, whilst on the other hand MCT are well absorbed. As taught above in the Niezen-Koning, MCT are administered to patients for the transfer of fatty acids across the mitochondrial membrane. Therefore one of ordinary skill in the art would be motivated to administer the MCT that can be easily transported to the plasma. See col. 1, lines 59-68.

Bach et al. (Am. J. Clin. Nutri. 1982; 950-962) is further introduced as it teaches that fat malabsorption is treated with MCT. The reference also teaches the deficiency of such (fat malabsorption) affects the skeletal muscle and in the systemic form the heart and liver and patients who suffer from deficiency of muscular carnitine have been successfully treated with MCT based diet, thus motivation to employ the formulation of Jandacek for the treatment of a translocase deficiency because MCT's are absorbed

faster than LCT's (long chain fatty acids). See pages 954, clinical uses under fat malabsorption and 956, rt. col. lines 3 from the top.

It would have been obvious to one of ordinary skill in the art to combine the cited prior art and administer a MCT, employ the formulation of Jandacek in treating a translocase deficiency such as deficiency of the carnitine system.

Maintained Double Patenting

The provisional obviousness type double patenting rejection is not the only rejection in the examined application and the rejection will continue to be made until the rejection is overcome as stated in MPEP 804 [R-5], I B, that "the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications." As noted above, the provisional obviousness double patenting rejection is not the only rejection remaining in this examined application. Thus rejection is maintained and is not held in abeyance.

Claims 17,19-47 and 49-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 25-27, 37-40, 42-45 and 47-56 of U.S. Patent No. 10/371,385. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 17,19-47 and 49-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-18 and 21-36 of copending Application No. 10/748432, in view of Rice et al., Neurology. Although the conflicting claims are not identical, they are not patentably distinct from each other

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Shirley V Gembeh/
Examiner, Art Unit 1618
9/10/08